


PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 109327:EJH:tjy	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001036	International Filing Date (day/month/year) 15 August 2003	Priority Date (day/month/year) 23 August 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 17/56 17/04, A61F 2/08		
Applicant KVINNO CENTRE PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 7 sheet(s).
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 12 February 2004	Date of completion of the report 23 July 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  DAVID MELHUISE Telephone No. (02) 6283 2426

I. Basis of the report**1. With regard to the elements of the international application:***☐ the international application as originally filed.

☒ the description, pages 2, 3, 5 - 18, as originally filed,
pages , filed with the demand,
pages 1, 4, received on 23 April 2004 with the letter of 23 April 2004

☒ the claims, pages 20, 22, as originally filed,
pages 19, 21, 23, received on 23 April 2004 with the letter of 23 April 2004
pages 24, received on 2 June 2004 with the letter of 2 June 2004
pages 25, received on 9 July 2004 with the letter of 8 July 2004

☒ the drawings, pages 1/20 - 20/20, as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:

pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language : which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages

☒ the claims, Nos. 2

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

See additional sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1, 3 - 49	YES
	Claims	NO
Inventive step (IS)	Claims 1, 3 - 49	YES
	Claims	NO
Industrial applicability (IA)	Claims 1, 3 - 49	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)Claims 1, 3-49:

Claims 1 and 3 to 49 meet the requirements of PCT Articles 33(2) - (4): None of the prior art documents, or obvious combination thereof, disclose a method of providing ligamentary support between two ligament and/or muscle locations in the body comprising connecting anchors fixed in each location by a filamentary element and then adjusting the tension of the element, nor do they disclose a tissue anchor for carrying out such a method. The prior art also does not disclose a holder for the tissue anchor or an insertion appliance for the tissue anchor.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box IV

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are four different inventions as follows:

1. Claims 1, 3 -16 are directed to a method of providing ligamentary like support comprising fixing two anchors, connecting the anchors by a filamentary element and adjusting the tension in the filamentary element. It is considered that *connecting two anchors by a filamentary element and adjusting the tension in the filamentary element* comprises a first "special technical feature".
2. Claims 17-34 are directed to a tissue anchor comprising a base and a head, the base including an aperture being adapted to receive a length of a filamentary element and only permitting unidirectional sliding movement. It is considered that *the aperture being adapted to receive a length of a filamentary element and only permitting unidirectional sliding movement* comprises a second "special technical feature".
3. Claims 35-43 are directed to a tissue anchor holder comprising a socket configured to receive the base and configured to allow access to the aperture and disengageable clamping engagement between the holder and the anchor. It is considered that *the disengageable clamping engagement between the holder and the anchor* comprises a third "special technical feature".
4. Claims 44-49 are directed to an insertion appliance for the tissue anchor comprising in combination a shaft, ejection means, bearing member and manipulation means to disengage the anchor from the holder. It is considered that *the shaft, ejection means, bearing member and manipulation means to disengage the anchor from the holder* comprises a fourth "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori. While the holder and the insertion appliance are by definition capable of being used with each other and the claimed anchor, there is no inventive concept or technical feature shared by the claim groups that represents a common advance over the prior art. However the International Search Report is sufficient for an opinion to be formed on all claims.

10/524701

BT01 Rec'd PCT/PT 16 FEB 2005

"Anchoring Device & its Implementation"

This invention relates to an anchor which can be used in surgical procedures on both humans and animals.

Background Art

The invention has application to a wide variety of surgical procedures and one such procedure relates to a method of resolving female incontinence, which involves insertion of a filament which is to be fixed to the ligamentous tissue to either side of the vagina in order to reconstitute the ligamentary support for the urethra and/or vaginal wall. In the past such filaments have either been fixed to the pubic bone or alternatively the rectus abdominous muscle or left "tension free" in that muscle.

The inventor is the principal author of an article entitled "Role of the Pelvic Floor in Bladder Neck Opening and Closure II: Vagina" which appeared in the International Urogynecology Journal (1997) 8:69-73. In that article it was identified the "connective tissue laxity in the vagina or its supporting ligaments is the prime cause of symptoms of stress, urgency and abnormal emptying". As a result in the case of a lax vagina, at least some of the muscular activity which is applied to maintain continence is taken up in resolving the vaginal laxity rather than control of the urethra. Therefore in rectifying the problem it is desirable to establish a situation in which the relationship between the existing muscular and ligamentary support can be re-established.

Disclosure of the Invention

Accordingly in one aspect the invention resides in a method of providing ligamentary like support between two spaced locations in the body of a patient wherein the locations comprise ligament and/or muscle tissue comprising fixing an anchor in each location, connecting the anchors by a filamentary element, adjusting the tension of the filamentary element between the locations to establish the desired spatial relationship between the locations to provide at least a supplementary ligamentary support between the locations.

According to a preferred feature of the invention the filamentary element is applied to at least one of the anchors prior to fixation. According to a preferred embodiment of the invention the filamentary element is applied to a pair of anchors at a spacing greater than that desired spatial relationship.

According to another aspect the invention resides in a tissue anchor formed of a material which is compatible for location in human and/or animal muscle and/or ligament tissue, the anchor comprising a base and a head, the head having a configuration to facilitate insertion of the head into tissue and retention of the head in the tissue once inserted, the base formed with an aperture adapted to receive a length of a filamentary element and permit slidable movement of the filamentary element through the aperture in one direction but to restrict movement of the filamentary element through the aperture in the opposite direction.

According to a preferred feature of the invention the aperture is associated with a locking element positioned to extend across the aperture to define a space between the locking element and an opposed edge of the aperture, said space being intended to receive the filamentary element, the locking member having one face proximate the one direction and another face proximate the opposite direction, the locking element intended to cooperate with the filamentary element when in position in the space to restrict the movement of the filamentary element in the opposite direction and to enable movement of the filamentary element in the one direction. According to a preferred feature the edge of the locking element defining the space is formed to engage the surface of the filamentary element when filamentary element is moved in the opposite direction. According to a preferred feature of the invention the edge is defined by a surface extending between the faces of the locking member, the surface being inclined away from the opposed edge of the aperture in the opposite direction. According to a preferred feature of the invention the edge is formed with slots which extend from the face proximate the one direction to at least an intermediate position across the surface. According to a preferred feature of the invention the face of the locking member proximate the one direction is formed as a recess inwardly of the edge. According to a preferred feature the locking member is inclined with respect to the base.

Claims

The claims defining the invention are as follows:

1. A method of providing ligamentary like support between two spaced locations in the body of a patient wherein the locations comprise ligament and/or muscle tissue comprising fixing an anchor in each location, connecting the anchors by a filamentary element, adjusting the tension of the filamentary element between the locations to establish the desired spatial relationship between the locations to provide at least a supplementary ligamentary support between the locations.
2. cancelled
3. A method as claimed at claim 1 or 2 wherein the anchors are provided with a retaining means adapted to be able to retain the filamentary element in a state of tension between the anchors.
4. A method as claimed at claim 3 wherein the retaining means enables movement of the filamentary element through the anchor to enable the length of the filamentary element between the locations to be shortened but to prevent movement of the filamentary element through the anchors to enable the length of the filamentary element between the applications to be increased.
5. A method as claimed at any one of the preceding claims wherein the filamentary element is not biodegradable over a period of time and is adapted to facilitate the growth of tissue between the locations to provide said ligamentary support between the locations.
6. A method as claimed at any one of the preceding claims wherein the anchor comprises a head having a configuration facilitating insertion into the tissue and retention of the head in the tissue once inserted, the anchor further having a base which is intended to receive the filamentary element, said method comprising inserting the head of the anchor into the tissue with the base buried in the tissue.

installing an anchor into the holder, placing the anchor in position in the tissue by manipulation of the appliance and on location of the anchor in the tissue, activation of the manipulation means to cause displacement of the anchor from the holder.

13. A method as claimed at any one of the preceding claims wherein the spaced locations comprise the recto-vaginal ligaments or the arcus tendineus ligaments to each side of the vagina and the method resides in the re-establishing of the fascial support for the vagina, said method comprising fixing said anchors into the recto-vaginal ligaments or the arcus tendineus ligaments respectively to each side of the vagina, applying the filamentary element between the anchors and introducing the filamentary element into the fascial tissue such that with time it will become embodied with the fascia and optimally tensioning the filamentary element between the anchors.
14. A method as claimed at any one of the preceding claims wherein the filamentary element is applied to at least one of the anchors prior to fixation.
15. A method as claimed at claim 14 wherein the filamentary element is applied to a pair of anchors prior to fixation at a spacing greater than the desired spatial relationship.
16. A method of providing ligamentary like support between two spaced locations in the body of a patient substantially as herein described.
17. A tissue anchor formed of a material which is compatible for location in human and/or animal muscle and/or ligament tissue, the anchor comprising a base and a head, the head having a configuration to facilitate insertion of the head into the tissue and retention of the head in the tissue once inserted, the base formed with an aperture adapted to receive a length of a filamentary element and permit slidable movement of the filamentary element through the aperture in one direction but to restrict movement of the filamentary element through the aperture in the opposite direction.

25. A tissue anchor as claimed at any one of claims 18 to 24 wherein the space has a part annular configuration.
26. A tissue anchor as claimed at any one of claims 18 to 25 wherein the space is located substantially centrally across the central longitudinal axis of the anchor.
27. A tissue anchor as claimed at any one of claims 18 to 26 wherein the face of the locking member proximate the one direction is formed as a recess inwardly of the edge.
28. A tissue anchor as claimed at any one of claims 18 to 27 wherein the locking member is inclined with respect to the base.
29. A tissue anchor as claimed at any one of claims 17 to 28 wherein the head has a barbed configuration.
30. A tissue anchor as claimed at claim 29 wherein the barbed configuration of the head is defined by a set of prongs, said prongs being located in substantially equi-distant spacing around the central axis of the head, said prongs being divergent away from the end of the head in the direction of base.
31. A tissue anchor as claimed at claim 30 wherein the prongs are of a tapered configuration.
32. A tissue anchor as claimed at claim 31 wherein the outer end of the prongs are pointed.
33. A tissue anchor as claimed at any one of claims 30 to 32 wherein the prongs are resiliently flexible along their length.
34. A tissue anchor substantially as herein described with reference to the accompanying
35. A holder adapted to support the anchor as claimed at any one of claims 17 to 34 comprising a socket configured to clampingly receive the base, the

- 24 -

socket being configured to allow access to the aperture, the clamping engagement between the holder and the base being such that on relative movement between the holder and the anchor the anchor is able to be disengaged from the holder.

36.A holder as claimed at claim 35 wherein the base has a substantially laminar-like configuration comprising two opposed substantially parallel faces.

37.A holder as claimed at claim 35 wherein the socket comprises a pair of spaced elements which receive opposed sides of the base with the aperture between the spaced elements.

38.A holder as claimed at claim 36 wherein the socket comprises a pair of spaced elements which receive opposed sides of the base with the aperture between the spaced elements.

39.A holder as claimed at claim 35 or 37 wherein the socket is defined by a set of boss elements which are configured to receive the free ends of the prongs of the tissue anchor as claimed at any one of claims 30 to 34 when compressed radially with respect to the central axis of the anchor.

40.A holder as claimed at any one of claims 35 to 39 supporting the anchor of the form as claimed at any one of claims 17 to 34 is provided as single element.

41.A holder as claimed at claim 40 including a length of said filamentary element supported by the anchor.

42.A pair of holders of the form as claimed at claim 41 supporting between themselves the length of the filamentary element.

43.A holder substantially as herein described with reference to the accompanying drawings.

44.An insertion appliance comprising a shaft adapted to accommodate at one end the holder as claimed at any one of claims 35 to 40, the other end of

- 25 -

the shaft supporting a handle, an ejection means extending between the one end and the handle, a bearing member provided at the one end and a manipulation means provided adjacent the handle whereby on an anchor of the form as claimed at any one of claims 17 to 34 being installed in the holder and on activation of the manipulation means the bearing member will bear upon the anchor to move the anchor from engagement with the holder.

45. An insertion appliance as claimed at claim 44 supporting the holder as claimed at any one of claims 35 to 43 and the holder supporting the anchor as claimed at any one of claims 27 to 34 provided as a single element.

46. An insertion appliance as claimed at claim 45 including a length of said filamentary element supported by the anchor.

47. A pair of insertion appliances of the form as claimed at claim 46 supporting between themselves the length of the filamentary element.

48. An insertion appliance as claimed at claim 48 provided with a pair of said holders which support between themselves the length of the filamentary element.

49. An insertion appliance substantially as herein described with reference to the accompanying drawings.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.